Remarks

Applicants appreciate the withdrawal of the rejections under 35 U.S.C. § 101 and 112, second paragraph.

The Amendments to the Claims

Claim 1 has been amended to delete a colon. This amendment complies with a requirement of form expressly set forth in the Final Office Action.

Claims 1 and 46 have been amended to recite that the claimed polypeptides have a "Δ^6 desaturase activity." The specification supports this amendment *inter alia* on page 6, line 1: "Particularly preferred desaturases of the invention are Δ^6 desaturases." This amendment responds directly to a point raised in the Final Office Action on page 3, last paragraph: "the specificity of the claimed desaturase is not stated."

Claim 4 is amended to recite that the polypeptide of claim 1 "comprises a histidine box" rather than "has at least one histidine box." This amendment is one of form only and does not change the scope of claim 4.

Claim 46 is amended to recite "at least 100 amino acids" rather than "a part" of the amino acid sequence shown in SEQ ID NO:2. See page 4, paragraph 5 of the specification: "Fragments of the polypeptides described above are also within the scope of the present invention, provided that they have desaturase activity These fragments are preferably at least 100 amino acids long." This amendment was not previously made because it addresses a rejection newly made in the Final Office Action. The amendment also presents claim 46 in better form for appeal.

The amendments do not add new matter and do not require a new search.

The Objection to Claim 1

The Office Action objects to the colon in claim 1. The colon has been deleted. Applicants respectfully request withdrawal of the rejection.

The Rejection of Claims 1-7, 12-14, and 46 Under 35 U.S.C. § 112, first paragraph

Claims 1-7, 12-14, and 46 stand rejected under 35 U.S.C. § 112, first paragraph, as not sufficiently described in the specification. Claims 2, 5-7 and 13 have been canceled. Applicants respectfully traverse the rejection of claims 1, 3, 4, 12, 14, and 46.

The first paragraph of 35 U.S.C. § 112 requires that the specification provide a written description of the claimed invention:

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Whether the specification meets the written description requirement for the claimed invention is a question of fact. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116. (Fed. Cir. 1991). The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that the applicants possessed the claimed subject matter as of the filing date sought. *Vas-Cath* at 1563-64, 19 U.S.P.Q.2d at 1117.

As last examined, claim 1 was directed to a genus of polypeptides (1) having desaturase activity, (2) comprising one or more amino acid deletions, insertions or substitutions relative to a polypeptide comprising the amino acid sequence as shown in SEQ ID NO:2, and (3) having at

least 90% amino acid sequence identity to SEQ ID NO:2. The Final Office Action asserts that the polypeptide comprising SEQ ID NO:2 (a Δ^6 desaturase) is not a representative species of the claimed genus "because the specificity of the claimed desaturase is not stated," because the claimed genus encompasses "for example, desaturase Δ^4, Δ^6, Δ^{12}," and because "no description has been provided of the common functional features of all polypeptides encompassed by the genus of the claims." Final Office Action, paragraph bridging pages 3 and 4.

To advance prosecution, claim 1 has been amended to recite that the claimed polypeptides have Δ^6 activity. Amended claim 1 now recites a genus of polypeptides which have a common function (Δ^6 desaturase activity) and of which the polypeptide of SEQ ID NO:2 is representative.

The Final Office Action rejects claim 46 "as lacking structural and functional description." Final Office Action, paragraph bridging pages 6 and 7. To advance prosecution, claim 46 has been amended to recite the structural feature of comprising at least 100 amino acids of the amino acid sequence as shown in SEQ ID NO:2 and the functional feature of having Δ^6 desaturase activity. Claim 46 as amended recites both structural and functional features sufficient to show that Applicants possessed the invention at the time the application was filed.

Applicants respectfully request withdrawal of the rejection.

The Rejection of Claims 1-7, 12, 14, and 44-46 Under 35 U.S.C. § 112, first paragraph

Claims 1-7, 12, 14, and 44-46 stand rejected under 35 U.S.C. § 112, first paragraph, as not enabled. The Final Office Action asserts that the specification does not support the broad scope of the claims. Final Office Action at page 9, first full paragraph. Claims 2, 5-7 and 13 have been canceled. Applicants respectfully traverse the rejection of claims 1, 3, 4, 12, 14, and 44-46.

Claims 1 and 46 are independent. The legal test for whether the specification enables generic claims 1 and 46 that "the scope of the claims must bear a *reasonable correlation* to the scope of enablement provided by the specification to persons of ordinary skill in the art." *In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. (BNA) 18, 24 (C.C.P.A. 1970) (emphasis added). As noted above, independent claims 1 and 46 have been amended and are now directed to a genus of polypeptides which have Δ^6 desaturase activity. Polypeptides of the genus recited in claim 1 comprise one or more amino acid deletions, insertions or substitutions relative to a polypeptide comprising the amino acid sequence as shown in SEQ ID NO:2 and have at least 90% amino acid sequence identity to SEQ ID NO:2. Polypeptides of the genus recited in claim 46 comprise at least 100 amino acids of the amino acid sequence as shown in SEQ ID NO:2.

The enablement the present specification provides reasonably correlates with the scope of the amended claims. The Final Office Action acknowledges that the level of skill in the art at the time the application was filed was high. Page 8, last paragraph. In light of this level of skill, the skilled artisan can make and prepare the claimed Δ^6 desaturases without resort to undue experimentation.

Amino acid substitutions in SEQ ID NO:2

With respect to amino acid substitutions, the specification offers the following guidance: "The skilled person is aware that various amino acids have similar characteristics. One or more such amino acids of a polypeptide can often be substituted by one or more other such amino acids without eliminating a desired property of that polypeptide (such as desaturase activity)." Page 7, lines 17-20. The specification further provides guidance as to which specific amino acid substitutions can be performed to arrive at functional desaturases. See page 7, line 21 through page 8, line 2. Thus functional polypeptides that contain amino acid substitutions relative to SEQ ID NO:2 could be produced by routine experimentation.

Deletions in SEQ ID NO:2

Functional desaturase polypeptides containing deletions relative to SEQ ID NO:2 also can be produced without undue experimentation. The level of skill in the art prior to the November 24, 1997 effective filing date of the application was such that it would have been routine for one of skill in the art to make deletions in the amino acid sequence as shown in SEQ ID NO:2 and to determine whether the resultant protein retained desaturase activity. See the references in Appendices 1-5 of the response filed _____. The discussion of these references in that response is incorporated here by reference. One of skill in the art could make deletions in a desaturase polypeptide comprising SEQ ID NO:2 and test its activity. The specification discloses tests to determine desaturase activity. See page 5, lines 25-28; page 22, lines 1-17; and page 23, lines 2-6. Thus, the experimentation required to produce and test the deleted desaturase polypeptides would merely be routine to those of skill in the art and is not undue.

Insertions in SEQ ID NO:2

Functional desaturase polypeptides containing insertions relative to SEQ ID NO:2 also can be produced without undue experimentation. The specification provides guidance for performing insertions in the desaturase amino acid sequence that will still produce a protein with desaturase function. The specification discloses that "[a]mino acid insertions . . . may be done to alter the nature of the polypeptide (e.g. to assist in identification, purification or expression)." Page 8, lines 10-12. These insertions may alter the polypeptide to "provide some protection against proteolytic cleavage." Page 6, lines 17-18. Other insertions can be, for example, "a signal sequence . . . to direct the transport of the polypeptide to a particular location within a cell or to export the polypeptide to a particular location within a cell or to export the polypeptide from the cell." Page 6, lines 20-22. The specification also teaches that insertions can be "moiet[ies] capable of being isolated by affinity chromatography." Page 6, line 23. Amino acids and amino acid sequences that perform these functions were well-known in the art prior to the effective filing date of the application. Thus, the experimentation required to produce the desaturase polypeptides with amino acid insertions would also merely be routine to those of skill in the art and not undue.

The requirement that the "full scope" of the claimed invention must be enabled has never been interpreted to require the enablement of every embodiment within the scope of the claims. *See, e.g., In re Wright*, 999 F.2d 1557, 1563, 27 U.S.P.Q.2d (BNA) 1510, 1515 (Fed. Cir. 1993); M.P.E.P. § 2164.03. Rather, to determine enablement, the examiner must weigh all the evidence, including the teachings of the specification. M.P.E.P. § 2164.05(a). In this case, the specification provides sufficient disclosure to enable one skilled in the art to make and use the

claimed Δ^6 desaturase polypeptides without undue experimentation.

Applicants respectfully request withdrawal of the rejection.

The Rejection of Claims 13 and 46 Under 35 U.S.C. § 102(b)

Claim 13 stands rejected under 35 U.S.C. § 102(b) as anticipated by a disclosure of "DL-methionine" in a 1990 Aldrich Chemical Company catalog. Claim 13 has been canceled.

Claim 46 stands rejected under 35 U.S.C. § 102(b) as anticipated by Thomas *et al.*, U.S. Patent 5,614,393 ("the '393 patent"). Applicants respectfully traverse this rejection.

To reject a claim as anticipated, each and every element as set forth in the claim must be either expressly or inherently described in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d (BNA) 1051, 1053 (Fed. Cir. 1987). The '393 patent does not disclose each element of claim 46 as amended.

The '393 patent is cited as teaching a desaturase that comprises a sequence of eight amino acids that is identical to the amino acids at positions 274-381 of SEQ ID NO:2. Claim 46 as amended, however, is directed to an isolated and purified polypeptide having desaturase activity and which comprises "at least 100 amino acids of the amino acid sequence shown in SEQ ID NO:2" As evidenced by the alignment provided with the Final Office Action, the '393 patent does not disclose such a polypeptide. Thus, the '393 patent does not anticipate claim 46.

Applicants respectfully request withdrawal of the rejection.

Respectfully submitted,

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Date: July 9, 2004

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